



HOME USE GUIDANCE WORKSHOP

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BRIEF HISTORY OF THE COMMITTEE

- **2001 Center Initiative**
- **Public and focused meetings**
- **Identified stakeholders**
- **Identified work items within the current regulatory purview**
- **Educational outreach through articles, public speaking, conferences**
- **Home use initiative 2010**

FIVE AREAS FOR HOME USE INITIATIVE

- **GUIDANCE FOR PRE AND POST MARKET DESIGN, TESTING, AND MONITORING**
- **WORK WITH ACCREDITING BODIES OF HOME HEALTH AGENCIES**
- **ENHANCE SURVEILLANCE**
- **LABELING REPOSITORY (60 day notice is out)**
- **OUTREACH TO PUBLIC**

TODAY'S ASSIGNMENT: HELP US MAKE A GOOD GUIDANCE DOCUMENT

- **LISTEN TO SPEAKERS**
- **ASK PERTINENT QUESTIONS**
- **LISTEN TO THE PUBLIC COMMENTS**
- **PARTICIPATE IN A BREAKOUT SESSION**
- **PROVIDE MORE FEEDBACK LATER**

WHAT WE SHOULD NOT FOCUS ON TODAY:

- **OTHER PORTIONS OF THE WHITE PAPER**
- **MARKETING ANY PRODUCT**
- **REIMBURSEMENT**
- **PROBLEMS YOU MAY HAVE WITH FDA**

FDA WILL:

- **TAKE ALL COMMENTS INTO CONSIDERATION**
- **PROVIDE FEEDBACK ON OUR THINKING**
- **PROVIDE THE TRANSCRIPT ON OUR WEBSITE**
- **ISSUE A DRAFT OF THE GUIDANCE FOR PUBLIC COMMENT IN 10 – 12 MONTHS**